



Pacific Consolidated Industries

K061414

JAN 22 2007

510(k) Summary

Expeditionary Deployable Oxygen Concentration System (EDOCS)
&
Mobile Oxygen Storage Tank (MOST)

Type of FDA Submission

Traditional 510(k)

Submitter Information

Submitter's Name: Pacific Consolidated Industries
Submitter's Address: 12201 Magnolia Avenue
Riverside, California 92503-4820
Owner/Operator ID: 9049531
Contact Person: Gary W. Clark
Submitter's Phone: (951) 479-0872 (Phone)
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Date of Preparation: January 12, 2007

Device Classification

Classification Name: Portable Oxygen Generator
Device Classification: 868.5440
Product Code: CAW
Panel: Anesthesiology and Respiratory Therapy Devices



Expeditionary Deployable Oxygen Concentration System (EDOCS)

Predicate Legally Marketed Device Equivalence

Substantial equivalence is claimed to the legally marketed predicate device previously submitted under K020330 – Deployable Oxygen Concentration System (DOCS).

Safe Medical Devices Act (SMDA) Statement

The oxygen supplied by the oxygen concentrator is supplemental and is not considered to be life supporting or life sustaining. The failure of the device would not have serious health consequences to the user.

Intended Use of Device

The Expeditionary Deployable Oxygen Concentration System (EDOCS-120B) is intended to generate and deliver USP grade 93% +/- 3% oxygen for supplemental oxygen use. This device is to be used only by trained personnel in disaster relief situations where bottled oxygen is not readily available.

Description of Device

The Expeditionary Deployable Oxygen Concentration System (EDOCS) is a family of devices that draw in normal air and produce oxygen. The EDOCS separates nitrogen from the air, producing an output of concentrated oxygen at 93 percent by the molecular sieve process. The final product contains not less than 90 percent and not more than 96 percent oxygen, by volume. The remainder of the product consists mostly of argon and nitrogen.

EDOCS employs an integral oxygen analyzer to provide control of oxygen purity.

The EDOCS device is an electromechanical device consisting primarily of a molecular sieve type oxygen concentrator, a compressor module(s), and one or more oxygen collection cylinders. The oxygen concentrator operates by adsorbing water and nitrogen from filtered air. Depending on the unit size, the resulting gas has increased oxygen at flow rates from 30 to 500 liters per minute at a pressure of 50 - 100 psi nominal and is capable of high pressure cylinder filling.

Device Labeling

The EDOCS is clearly labeled with the following:

- 93% ±3% Oxygen
- Contraindications, for example, oil-rich or flammable atmosphere
- Rx Only



Comparison of Technological Characteristics

The technological characteristics of these devices and their intended use to supply supplemental oxygen are the same as the predicate devices and raise no new questions of safety and effectiveness.

Special Controls/Conformance to Recognized Standards

The Expeditionary Deployable Oxygen Concentration System (EDOCS) conforms to the recognized standard USP 24-NF 19 (through Supplement Four, December 31, 2001) and employs an integral oxygen analyzer to provide control of oxygen purity in accordance with the standard.

The EDOCS has been tested under IEC 60601-1-2 and has passed the required Electromagnetic Compatibility tests.

A Risk Analysis, as described in ISO 14971, has been conducted on the EDOCS and all identified risks have been managed to the degree possible via design, engineering controls or labeling.

Summary of Performance Testing

Verification and validation testing activities were conducted to establish the performance and reliability characteristics of the EDOCS, to demonstrate performance as intended and substantial equivalency to predicate device. Testing involved the following areas:

- Purity
- Flow Rate
- Electrical Safety
- Mechanical
- Controls
- Device Performance

Acceptance criteria were based on US Army specifications (USAMMA), and those established in voluntary standards.

In all instances the device met all required performance criteria and functioned as intended, meeting the acceptance criteria.

Conclusions

In summary, Pacific Consolidated Industries has demonstrated that the EDOCS meets its specifications, is safe and effective for its intended use, and is substantially equivalent to the currently marketed devices.



Mobile Oxygen Storage Tank (MOST)

Predicate Legally Marketed Device Equivalence

Substantial equivalence is claimed to the legally marketed predicate device previously submitted under K040738 – Mobile Oxygen Storage Tank (MOST).

Safe Medical Devices Act (SMDA) Statement

The oxygen supplied by the MOST is supplemental and is not considered to be life supporting or life sustaining. The failure of the device would not have serious health consequences to the user.

Description of Device

The Mobile Oxygen Storage Tank (MOST) is a oxygen storage and distribution system consisting of lightweight, high strength, high-pressure, composite wound, brass lined cylinders and a distribution manifold secured within a rugged waterproof case. The MOST contains 10,000 liters of oxygen when filled to 2,250 psig (13,400 liters at 3,000 psig). The MOST has a maximum flow capability of 225 LPM, which is equivalent to 75 LPM per Oxygen Output fitting (3 fittings per MOST). These three oxygen output flows would typically be subdivided further by the customer's equipment.

The small footprint, relatively light weight and easy carrying of the MOST system make it optimal for emergency use and military deployments. Eight handles, two on each long side of the MOST and two on the top at each end are provided for ease of transportation. The MOST contains the Apparatus Kit, which includes the equipment required to distribute the oxygen to up to three patients concurrently. The exterior dimensions of the MOST are: a length of 37.25", a width of 27.18", and height of 15.44." The MOST weighs approximately 200 pounds when charged to 2,250 psig.

Intended Use of Device

The Mobile Oxygen Storage Tank (MOST) is intended to store and dispense USP grade 93% (+7%/-3%) oxygen at 50 psig nominal pressure for supplemental oxygen use. This device is to be used only by trained personnel in disaster relief situations where bottled oxygen is not readily available.

Device Labeling

The MOST is clearly labeled with the following:

- 93% +7%/-3% Oxygen
- Contraindications, for example, oil-rich or flammable atmosphere
- Rx Only



Comparison of Technological Characteristics

There are no significant changes in the design of the MOST unit in this submission from that of the original submission.

Special Controls/Conformance to Recognized Standards

The Mobile Oxygen Storage Tank (MOST) conforms to the DOT-CFFC standard.

A Risk Analysis, as described in ISO 14971, has been conducted on the MOST and all identified risks have been managed to the degree possible via design, engineering controls or labeling.

Summary of Performance Testing

Verification and validation testing activities were conducted to establish the performance, reliability and safety characteristics of the MOST and to demonstrate performance as intended. Testing involved the following areas:

- Purity
- Flow Rate
- Mechanical
- Controls
- Device Performance
- Safety

Acceptance criteria were based on USAF specifications (AFMESA), DOT-CFFC, NASA and MIL-STD-810F.

In all instances the device met all required performance criteria and functioned as intended, meeting the acceptance criteria.

Conclusions

In summary, Pacific Consolidated Industries has demonstrated that the MOST meets its specifications, is safe and effective in providing a portable supply of USP oxygen to the intended markets, and is substantially equivalent to the currently marketed device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 2007

Mr. Gary Clark
Vice President-Regulatory Affairs/ Quality Assurance
Pacific Consolidated Industries, LLC
12201 Magnolia Avenue
Riverside, California 92503-4820

Re: K061414

Trade/Device Name: Expeditionary Deployable Oxygen Concentration System
(EDOCS-120B)

Regulation Number: 868.5440

Regulation Name: Portable Oxygen Generator

Regulatory Class: II

Product Code: CAW

Dated: January 12, 2007

Received: January 16, 2007

Dear Mr. Clark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Statement of Indications for Use

Name: Expeditionary Deployable Oxygen Concentration System (EDOCS-120B)

The Expeditionary Deployable Oxygen Concentration System (EDOCS-120B) is intended to generate and deliver USP grade 93% +/- 3% oxygen for supplemental oxygen use. This device is to be used only by trained personnel in disaster relief situations where bottled oxygen is not readily available.


Name: Mobile Oxygen Storage Tank (MOST)

The Mobile Oxygen Storage Tank (MOST) is intended to store and dispense USP grade 93% (+7%/-3%) oxygen at 50psig nominal pressure for supplemental oxygen use. This device is to be used only by trained personnel in disaster relief situations where bottled oxygen is not readily available.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)


Mark A. Shew, M.D.
Chief, Anesthesiology, General Hospital,
FDA Control, Dental Devices
Number: K061414